

Application No. 08/928,272
Paper Dated: August 19, 2011
In Reply to USPTO Correspondence of April 26, 2011
Attorney Docket No. 3896-092985 (P-3818)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 08/928,272 Confirmation No. 9434
Appellant : MICHAEL ISKRA
Filed : September 12, 1997
Title : COLLECTION CONTAINER ASSEMBLY
Group Art Unit : 3771
Examiner : Kristen Clarette Matter

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

As discussed herein, Appellant respectfully submits that the rejections advanced in the Office Action dated April 26, 2011 are improper because they fail to establish a *prima facie* case that the claimed invention was obvious. A Notice of Appeal is submitted herewith. Because the April 26, 2011 Office Action reopened prosecution and advanced new rejections in response to a previously-filed Notice of Appeal and subsequent Appeal Brief filed by Appellant on March 30, 2011, no fees are due in connection with the current Notice of Appeal.

I. Claims 1, 6, and 9 were improperly rejected under 35 U.S.C. § 103(a) for obviousness based on the State of the Art in view of the Finney patent

Claims 1, 6, and 9 stand rejected under 35 U.S.C. § 103(a) for obviousness based on Figures 1 and 2 of the subject application, which is referred to in the Office Action as Applicant's Admitted Prior Art ("the State of the Art"), in view of United States Patent No. 4,358,425 to Finney et al. ("Finney"). This rejection is improper based on the art of record and should therefore be reversed.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on August 19, 2011.

08/19/2011
Date


Signature

Sharyn Beck

Typed Name of Person Signing Certificate

The claimed invention is directed to a one piece collection container assembly including a solid partition (76) positioned within the housing between a first end and a second end. The second end forms a false bottom which includes a bottom end that is below the partition. The bottom end has an annular skirt (78) and a semi-spherical bottom (80) which has an opening (82) therein. (*See, e.g.*, Figs. 3 and 4.)

Figures 1 and 2 of the subject application show a prior art false bottom specimen container, having a sidewall with an outer surface (14) and an inner surface (16). An annular skirt (28) extends from the lower portion (20) and the outer surface (14) to a flat planar bottom end (30) to define a false bottom (32). The bottom end is flat, not semi-spherical.

The Finney patent is directed to a centrifuge tube useful for obtaining analytical samples having a rounded bottom (12) containing a passageway (14). A tight fitting, resilient plug (20), pierceable by a hypodermic syringe (26), is disposed in the passageway, and the plug (20) provides a leak-tight closure for the passageway (14) and the recesses (16, 18) (Finney, column 2, lines 26-39). This centrifuge tube arrangement allows for a sedimentation fraction that has accumulated at the bottom of the tube to be removed through the bottom of the tube (rather than through the top of the tube) by piercing the plug with the needle of the hypodermic syringe and drawing out the fraction which has settled at the bottom of the tube (Finney, column 2, lines 36-41). Finney states “[i]n this way, the constituents of a desired strata may be withdrawn from the tube without having it remix with adjacent layers” (Finney, column 2, lines 41-43).

As recognized by the Examiner, the State of the Art did not include a false-bottomed tube where the bottom of the tube is semi-spherical. Nonetheless, the Examiner concludes it would have been obvious in view of Finney to modify known false bottom collection containers (like that shown in Figures 1 and 2 of the subject application) to include a bottom edge that is semi-spherical. However, the reasoning employed by the Examiner to reach this conclusion fails to explain why the proposed modification would (rather than could) be made, is not based on a fair characterization of the prior art, and improperly applies teachings from the Appellant’s own disclosure. Therefore, because the Examiner has not met her burden of establishing a *prima facie* case of obviousness, the rejection must be reversed.

First the Examiner attempts to support the conclusion of obviousness by stating that “absent a critical teaching and/or showing of unexpected results from the tube having a

semi-spherical bottom,” modifying the bottom end of the tube shown in Figures 1 and 2 of the subject application so that it is semi-spherical is “an obvious design consideration” that does not patentably distinguish over the prior art. (Office Action, pages 3-4.) However, as the Examiner acknowledges, “[c]hanging the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube.” *Id.* In other words, the claimed design allows the claimed false-bottomed collection tube, despite having a false-bottom, to be used in standard clinical equipment, which was not possible with prior art false bottomed tubes. When, like here, the modification of the shape of the claimed object changes the operation of the object, the change is not a “mere design choice” as the Examiner contends. *Cf. In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (shifting the position of the starting switch held to be unpatentable since it would not have modified the operation of the device); MPEP § 2144.04 VI. C. Simply because one skilled in the art could modify the shape of a prior art device to meet the terms of the claims is not by itself sufficient to support a finding of obviousness or otherwise make the modification an “obvious design consideration”.

Second, the Examiner argues that it would be obvious to modify the bottom end of the tube shown in Figures 1 and 2 of the subject application so that it is semi-spherical because Figure 1 and the abstract of Finney allegedly discuss how such a semi-spherical shape allows the tube to be used in the cavity of a centrifuge rotor. (Office Action page 4.) However, this is not a fair characterization of the actual teachings of Finney. The abstract of Finney, for example, includes nothing that suggests, let alone teaches, that the shape of the bottom of the tube is what allows the tube to be useable in the cavity of a centrifuge rotor. The statement in the abstract regarding the use of the tube in the cavity of the rotor and the separate statement that the tube has a rounded bottom are independent from one another, and together do not imply that only rounded bottom tubes can be used in a centrifuge. In other words, because the tube is used in a centrifuge and has a rounded bottom, it does not necessarily follow that tubes not having a rounded bottom could not be used in a centrifuge. Indeed, the preferable use of the container in the also relied upon Burns patent (U.S. Patent No. 5,458,854), which does not have a rounded bottom, is in a micro-centrifuge (Burns, column 2, lines 43-44) or, with the aid of a flat-bottomed extension, in a normal centrifuge (Burns, column 5, lines 13-17). The previously-relied upon

Drier patent (U.S. Patent No. 5,038,958), cited as allegedly teaching a false bottom container, similarly discusses the importance of a flat-bottomed, cylindrical outer shell to allow the tube to stand upright on a flat surface.

In view of the shortcomings of the Examiner's two arguments discussed above, the Examiner's conclusion that it would have been obvious to modify the prior art tube to have a rounded bottom "depending on the use of the device" or "to allow compatibility with standard clinical centrifuge equipment" appears to be based not on Finney, but rather on the specification of the subject application itself. Indeed, while Finney fails to provide either of these motivations to modify the prior art tube, the subject specification states that a "further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation" (Specification, page 5, lines 21-23). Of course, it is axiomatic that the obviousness determination cannot be based on knowledge gleaned from Appellant's disclosure but must instead be based on the state of the art at the time the subject application is filed. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

Moreover, even if the references are properly combined, the teachings of these references as a whole do not render all of the claim features obvious. As noted, the claimed invention recites a semi-spherical bottom with an opening therein. The bottom end of the Finney tube, however, does not contain an opening therein, which is recited in the claimed container. Instead, Finney discloses a closed bottom container, incorporating a tight fitting, resilient plug, pierceable by a hypodermic syringe, disposed in a passageway to provide a leak-tight closure. Indeed, the Finney tube cannot have an opening in the bottom end because Finney is not directed to a false bottom container. If Finney contained an opening in the bottom end, the contents in the container would simply fall right through. On the other hand, a false bottom container can have an opening in the bottom end due to the partition located between the top end and bottom end which forms the "true" bottom of the container. Thus, modifying known prior art false bottomed containers to have the bottom end of Finney (as proposed in the Office Action) would fail to meet the limitation in the claims directed to the opening in the bottom end of the container.

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Therefore, the rejection of claims 1, 6, and 9 under 35 U.S.C. § 103(a) for obviousness based on Figures 1 and 2 of the subject application in view of Finney is improper and should be reversed.


II. Claims 5, 7, and 8 were improperly rejected under 35 U.S.C. § 103(a) for obviousness based on the State of the Art and Finney and further in view of Burns.

Claims 5, 7, and 8 stand rejected under 35 U.S.C. § 103(a) for obviousness based on the State of the Art and Finney and further in view of United States Patent No. 5,458,854 to Burns. These claims depend from claim 1. Because additional reference to Burns fails to cure the deficiencies of the State of the Art and Finney discussed above, this rejection is also improper. In fact, Burns teaches away from the claim by specifically requiring that the bottom end of the tube includes a cylindrical shape for receiving a portion of the cap thereon. (Burns, column 5, lines 7-12). Therefore, this rejection should also be reversed.

III. Conclusion

In view of the above specified numerous clear errors and deficiencies, Appellant asserts that a *prima facie* case of obviousness has not been established. It is therefore respectfully requested that the rejections be reversed and the application be returned to the Examiner with instruction to allow pending claims 1 and 5-9.

Respectfully submitted,
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